Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

October 3, 2014

Senator John A. Alario Jr., President
Louisiana Senate
PO Box 94183
Baton Rouge, LA 70804

Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for Regulatory Project 2014-3 ~ Pharmacy Records

Dear Senator Alario:

As we indicated in our first report to you on March 10, 2014, the Board is currently amending its rules relative to recordkeeping requirements in pharmacies. Subsequent to our Notice of Intent published in the March 20, 2014 edition of the *Louisiana Register*, and in accordance with the Administrative Procedures Act, we conducted a public hearing at the Board office on April 29, 2014.

We received no written comments; however, during the public hearing, we received questions from two commentators. The Board considered those comments during their subsequent meeting on May 7. During that meeting, the Board directed staff how to respond to the commentators, and further, agreed with a request from one of the commentators for some suggested revisions to the original proposed rule as published in the Notice of Intent. The Board sought and received an opinion from the Legislative Fiscal Office that the proposed revisions would not adversely impact any pharmacy and could actually lower some costs for some pharmacies. We prepared a modified Fiscal & Economic Impact Statement which was approved by the Legislative Fiscal Office on August 5. With that prerequisite, we published a Potpourri Notice in the August 20, 2014 edition of the *Louisiana Register*. In accordance with the Administrative Procedures Act, we conducted a second public hearing on the proposed revisions at the Board office on September 30, 2014.

Prior to the second public hearing, we received no written comments, and the three commentators at the hearing asked questions regarding implementation and record retention requirements. There were no concerns, objections, or requests for further changes. The Board has determined it appropriate to move forward with the proposed rule including the revision.

You should find the following documents appended to this letter:

- Notice of Intent, as published in the March 2014 *Louisiana Register*
- Summary of Comments at April 29, 2014 Public Hearing
- Board Responses to Commentators from April 29, 2014 Public Hearing
- Revised Fiscal & Economic Impact Statement from August 5, 2014
- Potpourri Notice, as published in the August 2014 *Louisiana Register*
- Summary of Comments at September 30, 2014 Public Hearing
- Board Responses to Commentators from September 30, 2014 Public Hearing
- Full text of proposed rule as revised

Subject to review by the Joint Legislative Oversight Committee on Health and Welfare, the Board proposes to publish the revised proposed rule as a Final Rule in the November 20, 2014 edition of the *Louisiana Register*, to become effective on January 1, 2015. If you have any questions about the enclosed information or our procedures, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm Broussard

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Committee on Health and Welfare – APA.S-H&W@legis.la.gov
Speaker, House of Representatives – APA.HouseSpeaker@legis.la.gov
Chair, House Committee on Health and Welfare – APA.H-H&W@legis.la.gov
Editor, *Louisiana Register* – Catherine.Brindley@la.gov
Reference File

Notice of Intent

Department of Health and Hospitals
Board of Pharmacy

Pharmacy Records (LAC 46:LIII.Chapters 11, 12, and 15)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy hereby gives notice of its intent to amend several sections within *Chapter 11 – Pharmacies*, as well as Section 1213 in *Chapter 12 – Automated Medication Systems* and Sections 1503 and 1509 in *Chapter 15 – Hospital Pharmacy* to update the rules relative to pharmacy records and recordkeeping requirements.

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

…

Subchapter B. Pharmacy Records

§1119. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
"Department" means the Louisiana Department of Health and Hospitals or its successor.
"Password" means a private identification that is created by a user to obtain access to an electronic pharmacy information system.
"Personal identifier" means a unique user name or number for identifying and tracking a specific user's access to a pharmacy information system such as social security number, user identification number, or employee number.
"Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a prescription drug.

1. A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
    a. A manual signature on a hard copy record;
    b. A magnetic card reader;
    c. A bar code reader;
    d. A thumbprint reader or other biometric method;
    e. A proximity badge reader;
    f. A register in which each individual pharmacist dispensing a prescription shall sign a log each day, attesting to the fact that the information entered into the electronic record keeping system has been reviewed that day, and is correct as stated.
    g. A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the prescription drug. The printout must be maintained for two years and made available on request to an agent of the board.
2. A method relying on a magnetic card reader, a bar code reader, or a proximity badge reader must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR

§1121. General Requirements

A. Requirements.
    1. All records relating to the practice of pharmacy shall be uniformly maintained for a period of two years, be readily available, and promptly produced upon request for inspection by an agent of the board during regular business hours.
    2. All records required by the laws and regulations of the board shall be provided to the board, or its agents, within seventy-two (72) hours of request, unless a shorter period is required, as determined by the board or its agent.
    3. The failure to produce any pharmacy records requested by the board or its agent within seventy-two (72) hours of such request shall substantiate a violation of R.S. 37:1241(A)(22).
B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all prescription drug transactions, consisting of:
    1. Acquisition records – invoice receipts of drugs acquired;
    2. Disposition records – drugs dispensed pursuant to prescription orders, administered pursuant to medical orders, or distributed pursuant to purchase orders, and
    3. Inventory records – drugs in current possession.

C. Retention. Except as provided in Section 1123, all records required by this Chapter and by Louisiana law shall be retained for a minimum of two years from the most recent transaction. The failure to retain such records for at least two years shall substantiate a violation of R.S. 37:1229.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR

§1123. Records

A. There shall be positive identification of the pharmacist, intern, technician, or technician candidate responsible for performing all activities related to the practice of pharmacy including, but not limited to:
    1. Prescription information entered into the pharmacy information system;
    2. Prospective drug utilization review;
    3. Prescription dispensing;
    4. Administration of immunizations.

B. A pharmacy may use one of the following types of pharmacy information systems:
    1. A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system shall require the manual signature or initials of a pharmacist on a hard copy record as specified in Paragraph E of this Section.
    2. An electronic recordkeeping system that complies with the provisions of 21 CFR 1311 and documents the positive identification of the pharmacist responsible for the practice of pharmacy. Such systems shall provide for routine backups at least once per day.

C. All pharmacy information systems shall be capable of providing immediate retrieval (via display and hard copy printout or other mutually agreeable transfer media) of patient profile information for all prescriptions dispensed within the previous two years. This information shall include the following minimum data:
    1. The original prescription number;
    2. Date of issuance of the original prescription order by the prescriber;
    3. Date of dispensing by the pharmacist;
    4. Full name and address of the patient;
    5. Full name and address of the prescriber;
    6. Directions for use;
    7. The name, strength, dosage form, and quantity of the drug prescribed;
    8. The quantity dispensed if different from the quantity prescribed;
    9. The pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in §515 of these rules, and the pharmacist responsible for dispensing;
    10. The total number of refills authorized by the prescriber; and
    11. The refill history of the prescription as defined in Paragraph D of this Section.

D. The refill history of the prescription record maintained in the pharmacy information system shall include, but is not limited to:
    1. The prescription number;
    2. The name and strength of the drug dispensed;
    3. The date of the refill or partial fill;
    4. The quantity dispensed;
    5. The pharmacist responsible for prospective drug utilization review as defined in §515 of these rules, and the pharmacist responsible for dispensing each refill;
    6. The total number of refills or partial fills dispensed to date for that prescription order

E. The hard copy documentation required pursuant to Paragraph (B)(1) of this Section shall be provided by each individual pharmacist who makes use of such system by signing a statement attesting to the fact that the prescription information entered into the computer is correct as displayed.

F. Backup Support System
    1. The pharmacy information system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic

records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.

2. In the event the pharmacy information system experiences down time, a record of all refills dispensed during such time shall be recorded and then entered into the pharmacy information system as soon as it is available for use. During the time the pharmacy information system is not available, prescriptions may only be refilled if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

G. A pharmacy purging a pharmacy information system of prescription records shall develop a method of recordkeeping capable of providing retrieval (via display, hard copy printout, or other mutually agreeable transfer media) of prescription order information for all prescriptions filled or refilled within the previous two years. This information shall include, at a minimum, the following data:

1. Pharmacy name and address;
2. Original prescription number;
3. Date of issuance of the original prescription order by the prescriber;
4. Date of original dispensing by the pharmacist;
5. Full name and address of the patient;
6. Full name and address of the prescriber;
7. Directions for use;
8. Name, strength, dosage form, and quantity of the drug prescribed;
9. Quantity dispensed if different from the quantity prescribed;
10. Total number of refills authorized by the prescriber;
11. Total number of refills dispensed to date for that prescription order;
12. Date of each refill;
13. Name or initials of each individual dispensing pharmacist.

H. A log shall be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. At a minimum, the log shall contain the following information:

1. Date and time of change;
2. Change(s) made;
3. Pharmacist making the change.

I. Prescriptions entered into a pharmacy information system but not dispensed shall meet all of the following requirements:

1. The complete prescription information shall be entered in the computer system;
2. The information shall appear in the patient's profile; and
3. There is positive identification, in the pharmacy information system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system.

J. With respect to oral prescriptions received in the pharmacy and then transcribed to written form in the pharmacy, or written prescriptions received by facsimile in the pharmacy, or written prescriptions presented to the pharmacy, a pharmacy may use an electronic imaging system to preserve such prescriptions, but only if:

1. The system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription form;
2. Any notes of clarification of and alterations to a prescription shall identify the author and shall be directly associated with the electronic image of the prescription form;
3. The image of the prescription form and any associated notes of clarification to or alterations to a prescription are retained for a period of not less than two years from the date the prescription is last dispensed;
4. Policies and procedures for the use of an electronic imaging system are developed, implemented, reviewed, and available for board inspection; and
5. The prescription is not for a controlled dangerous substance listed in Schedule II

K. Filing and Retention of Prescription Forms

1. Written prescription forms (including transcriptions of verbal prescriptions received in the pharmacy, prescriptions received by facsimile in the pharmacy, as well as written prescription forms presented to the pharmacy) shall be assembled and stored in prescription number sequence. Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately from all other prescriptions. Where multiple medications are ordered on a single prescription form and includes one or more controlled dangerous substances listed in Schedule II, then such forms shall be filed with other Schedule II prescriptions. These

original hard copy prescription forms shall be retained in the prescription department for a minimum of two years following the most recent transaction.

2. For those pharmacies utilizing an electronic imaging system as described in Paragraph J of this Section, written prescription forms may be assembled and stored in prescription number sequence, or in the alternative, a date scanned sequence. Further, these original hard copy prescriptions shall be retained in the prescription department for a minimum of one year following the most recent transaction.
3. Prescription forms received as an electronic image or electronic facsimile directly within the pharmacy information system shall be retained within the information system for a minimum of two years following the most recent transaction. Further, the pharmacy may produce a hard copy of the prescription form but shall not be required to do so merely for recordkeeping purposes.
4. Electronic prescriptions – those generated electronically by the prescriber, transmitted electronically to the pharmacy, and then received electronically directly into the pharmacy information system – shall be retained within the information system for a minimum of two years following the most recent transaction. The pharmacy may produce a hard copy of the prescription, but shall not be required to do so merely for recordkeeping purposes.

L. Patient Profiles

All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.

1. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, document, and maintain at least the following records:
    a. The patient's data record, which should consist of, but is not limited to, the following information:
        i. Full name of the patient for whom the drug is intended;
        ii. Residential address and telephone number of the patient;
        iii. Patient's date of birth;
        iv. Patient's gender;
        v. A list of current patient specific data consisting of at least the following:
            (aa) Known drug related allergies,
            (bb) Previous drug reactions,
            (cc) History of or active chronic conditions or disease states,
            (dd) Other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices.
        vi. The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug.
    b. The patient's drug therapy record, which shall contain at least the following information for all the prescriptions that were filled at the pharmacy:
        i. Name and strength of the drug or device;
        ii. Prescription number;
        iii. Quantity dispensed;
        iv. Date dispensed;
        v. Name of the prescriber;
        vi. Directions for use.
    c. Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.

M. Exceptions

The provisions of this Section shall not apply to the following:

1. Pharmacies permitted as hospital pharmacies by the board shall comply with the provisions of Chapter 15 of these rules.
2. Other pharmacies providing medications and services to patients within facilities other than hospitals licensed by the department shall comply with the provisions of Section 1124 of these rules for those activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 36:755 (April 2010), amended LR

§1124. Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other than Hospitals

A. Definitions

Dispensing of a drug pursuant to an inpatient prescription – the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated medication system meeting the requirements of Chapter 12 of these rules, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given the final approval to the patient specific order in the system.

Electronic drug record keeping system – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

Inpatient – a person receiving health care services within a healthcare facility other than a hospital licensed by the department.

Inpatient Prescription – a written, electronic or oral order for a drug for use in treating a patient within a healthcare facility other than a hospital licensed by the department.

Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

Personal identifier – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number

Positive identification – has the same meaning as defined in Section 1119 of these rules, except that a specific facility having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:

1. adequate audit controls are in place to detect and deter drug diversion;
2. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
3. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
4. an ongoing quality assurance program is in place to ensure that (a) through (c) of this term are being fulfilled and reviewed; and
5. appropriate policies and procedures are in place to address items (a) through (d) of this term.

All of the above notwithstanding, however, positive identification as defined in Section 1119 of these rules shall always be used to document the:

a. Dispensing, compounding, or prepackaging of a drug;
b. Removal and possession of a controlled substance to administer to a patient; and
c. Waste of a controlled substance.

B. Drug Distribution and Control

The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs.

1. Procedure Manual. The pharmacist-in-charge shall maintain defined procedures for the safe and efficient distribution of medications and pharmacy care. A current copy of the manual shall be available for board inspection upon request.
2. Inventories. The pharmacist-in-charge shall be responsible for the performance of an annual inventory of all controlled dangerous substances within his span of control, in compliance with the provisions of Section 2733 of these rules.
3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
    a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
    b. All drug orders and records relating to the practice of pharmacy.

i. Records of drugs dispensed shall include, but are not limited to:
(aa) The name, strength, and quantity of drugs dispensed;
(bb) The date of dispensing;
(cc) The name of the inpatient to whom, or for whose use, the drug was dispensed; and
(dd) Positive identification of all pharmacists involved in the dispensing.

ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
(aa) The name of the inpatient to whom, or for whose benefit, the activity was performed;
(bb) The nature of the pharmacy practice activity performed;
(cc) The results of the activity, if applicable; and
(dd) Positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist.

iii. Records of drugs dispensed to patients for use outside the facility shall be maintained in compliance with Section 1123 of these rules.

c. A record of all drugs compounded or prepackaged for use only within that facility, which shall include at least the following:
i. Name of drug, strength, quantity, and dosage form;
ii. Manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
iii. Manufacturer's or distributor's name, if a generic drug is used;
iv. Pharmacy control number;
v. Manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
vi. Pharmacy's expiration date or beyond-use date;
vii. Positive identification of the licensed person responsible for the compounding or prepackaging of the drug.

d. A record of the distribution of drugs to patient care areas and other areas of the facility held for administration, which shall include at least the following:
i. The name, strength, dosage form, and amount of the drug distributed;
ii. The area receiving the drug;
iii. The date distributed;
iv. Positive identification of the individual receiving the drug if it is a controlled dangerous substance;
v. The area of the facility receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
(aa) Name of the patient;
(bb) Name, dosage form, and strength when applicable of the drug;
(cc) Date and time the drug was administered;
(dd) Quantity administered;
(ee) Positive identification of the personnel administering the drug.

e. A log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
i. Date and time of change;
ii. Changes made;
iii. Person making the change.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR

§1125. Security and Confidentiality

A. The holder of the pharmacy permit shall provide adequate safeguards against improper, illegal, or unauthorized manipulation or alteration of any records in the pharmacy information system.

B. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential information. If confidential health information is not transmitted directly between a

pharmacist and a practitioner, but is transmitted through a data communications device, the confidential health information may not be accessed, maintained, or altered by the operator of the data communications device. Confidential information is privileged and may be released only subject to federal privacy laws and regulations, and subject to applicable Louisiana statutes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23.1312, (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, amended LR

§1127. Register
Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, repealed LR

§1129. Confidentiality
Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004, repealed LR

…

Chapter 12. Automated Medication Systems

…

§1213. Records
A. Records and/or electronic data kept by the system shall meet the following requirements:
1. …
2. In the event controlled substances are stored in the system, the records shall include the positive identification (as defined in Section 1119 of the Board's rules) of the personnel retrieving and administering the controlled substance to the patient.
3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000), effective July 1, 2000, amended LR

…

Chapter 15. Hospital Pharmacy

…

§1503. Definitions
Dispensing of a drug pursuant to a hospital prescription – the professional review by a pharmacist required to place a specific drug in final association with the name of a particular hospital patient pursuant to the lawful order of a prescriber. In the case of an automated medication system meeting the requirements of Chapter 12 of these rules, the final association with the name of a particular hospital patient will be deemed to have occurred when the pharmacist has given the final approval to the patient specific order in the system.
Electronic drug record keeping system – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.
Hospital Patient – a person receiving health care services within a hospital facility.

Hospital Pharmacy – …
Hospital Prescription – a written, electronic or oral order for a drug for use in treating a hospital patient.
Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.
Personal identifier – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number
Positive identification – has the same meaning as defined in Section 1119 of these rules, except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:

1. adequate audit controls are in place to detect and deter drug diversion;
2. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
3. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
4. an ongoing quality assurance program is in place to ensure that all three provisions cited above in this definition are being fulfilled and reviewed; and
5. appropriate policies and procedures are in place to address all four provisions cited above in this definition.

All of the above notwithstanding, however, positive identification as defined in Section 1119 of these rules shall always be used to document the:

a. Dispensing, compounding, or prepackaging of a drug;
b. Removal and possession of a controlled substance to administer to a patient; and
d. Waste of a controlled substance.

Unit Dose – …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007), amended LR

…

§1509. Drug Distribution and Control

A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs. The staff of the hospital pharmacy shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.

1. Procedure Manual
   …
2. Inventories
   …
3. Records
   The pharmacist-in-charge shall be responsible for maintaining the following records:
   a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
   b. All drug orders and records relating to the practice of pharmacy.
      i. Records of drugs dispensed shall include, but are not limited to:
         (aa) The name, strength, and quantity of drugs dispensed;
         (bb) The date of dispensing;
         (cc) The name of the hospital patient to whom, or for whose use, the drug was dispensed; and
         (dd) Positive identification of all pharmacists involved in the dispensing.

ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
(aa) The name of the hospital patient to whom, or for whose benefit, the activity was performed;
(bb) The nature of the pharmacy practice activity performed;
(cc) The results of the activity, if applicable; and
(dd) Positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist.
iii. Records of drugs dispensed to patients for use outside the hospital shall be maintained in compliance with Section 1123 of these rules.

c. A record of all drugs compounded or prepackaged for use only within that hospital, which shall include at least the following:
i. Name of drug, strength, quantity, and dosage form;
ii. Manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
iii. Manufacturer's or distributor's name, if a generic drug is used;
iv. Pharmacy control number;
v. Manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
vi. Pharmacy's expiration date or beyond-use date;
vii. Positive identification of the licensed person responsible for the compounding or prepackaging of the drug.

d. A record of the distribution of drugs to patient care areas and other areas of the hospital held for administration, which shall include at least the following:
i. The name, strength, dosage form, and amount of the drug distributed;
ii. The area receiving the drug;
iii. The date distributed;
iv. Positive identification of the individual receiving the drug if it is a controlled dangerous substance;
v. The area of the hospital receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
(aa) Name of the patient;
(bb) Name, dosage form, and strength when applicable of the drug;
(cc) Date and time the drug was administered;
(dd) Quantity administered;
(ee) Positive identification of the personnel administering the drug.

e. A log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
i. Date and time of change;
ii. Changes made;
iii. Person making the change.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004, amended LR

…

FAMILY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency rule.

I. The effect on the stability of the family.

We anticipate no effect on the stability of the family.

II. The effect on the authority and rights of parents regarding the education and supervision of their children.

We anticipate no effect on the authority and rights of parents regarding the education and supervision of their children.

III. The effect on the functioning of the family.

We anticipate no effect on the functioning of the family.

IV. The effect on family earnings and family budget.

We anticipate no effect on family earnings and the family budget.

V. The effect on the behavior and personal responsibility of children.

We anticipate no effect on the behavior and personal responsibility of children.

VI. The ability of the family or a local government to perform the function as contained in the proposed rule.

We anticipate no effect on the ability of the family or a local government to perform the activity as contained in the proposed rule.

POVERTY IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the rule proposed for adoption, repeal, or amendment.

I. The effect on household income, assets, and financial security.

We anticipate no impact on household income, assets, and financial security.

II. The effect on early childhood development and preschool through postsecondary education development.

We anticipate no impact early childhood development or preschool through postsecondary education development.

III. The effect on employment and workforce development.

We anticipate no positive impact on employment and workforce development.

IV. The effect on taxes and tax credits.

We anticipate no impact on taxes or tax credits.

V. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

We anticipate no impact on child and dependent care, housing, health care, nutrition, transportation, or utilities assistance.

REGULATORY FLEXIBILITY ANALYSIS
FOR ADMINISTRATIVE RULES

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses:

I. The establishment of less stringent compliance or reporting requirements for small businesses.

The proposed rule allows small pharmacies to continue their method of compliance or reporting requirements.

II. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

There are no changes in the deadlines for compliance or reporting requirements for small businesses.

III. The consolidation or simplification of compliance or reporting requirements for small businesses.

The proposed rule allows small pharmacies to continue their current reporting systems.

IV. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed rule.

The proposed rule permits small pharmacies to maintain their current recordkeeping systems.

V. The exemption of small businesses from all or any part of the requirements contained in the proposed rule.

There are no exemptions from any of the requirements, but there are allowances for alternative methods of compliance.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule. A public hearing on this proposed rule is scheduled for Tuesday, April 29, 2014 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The Board has allocated $1,000 for printing costs of the proposed rule in the current fiscal year and the same amount for printing of the final rule in FY 2014-2015. The proposed rule will result in no costs or savings to local governmental units. The proposed rule changes requirements relative to pharmacy records, establishes standards for the receipt and processing of electronic prescriptions, and clarifies and updates requirements regarding confidentiality, pharmacy records, and records retention.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no impact on state or local government revenue collections from the proposed rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule will affect all pharmacies with respect to their dispensing information systems. Some pharmacies already comply with the new standards and some do not. There could be an indeterminable cost for some pharmacies to upgrade their information system technology. Alternatively, pharmacies may elect to maintain their current record keeping system as long as the system complies with certain provisions as detailed in §1123, Paragraph B.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will not have any effect on competition or employment.

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

Summary of Testimony & Public Comments
re
Regulatory Project 2014-3 ~ Pharmacy Records
at
April 29, 2014 Public Hearing

1. Observer with no comments – Bradley Westmoreland on behalf of Genentech

2. Danny O. Donato, appearing on behalf of Omnicare Pharmacies

Questioned the necessity of positive identification for delivery of controlled substances to patient care areas as described in §1124.B.3.d.iv.

Questioned whether the positive identification requirement for compounding and prepackaging described in §1124.B.3.c.vii referenced such activities in the licensed pharmacy.

Questioned whether the proposed rule addressed the electronic storage of faxed prescriptions received in pharmacies serving patients in long term care facilities. In particular, would the provisions of §1123.J be applicable to such pharmacies, or should similar language be added to §1124?

3. Paul J. D'Aunoy, representing himself

Questioned the interaction of the proposed rule with the current requirements of the remote processing rule in §1143 of the Board's rules. In particular, he questioned whether the agreement required in §1143.A.1.a could delineate which of the parties would be responsible for compliance with the various recordkeeping requirements in the proposed rule, or would both parties be required to maintain duplicate copies of all required records.

4. Observer with no comments – Corey Pate, on behalf of La. Independent Pharmacies Assoc.

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

June 11, 2014

Danny O Donato
Omnicare of New Orleans
660 Distributors Row Ste A
River Ridge, LA 70123-3243

Re: Regulatory Project 2014-3 ~ Pharmacy Records

Dear Mr. Donato:

Thank you for taking the time to review the Board's proposed amendments to its rules relative to pharmacy records, as well as for participating in the Board's public hearing on April 29 to receive comments and testimony on the proposed amendments. During the hearing you raised three questions about the proposed amendments – two relative to the necessity for positive identification for two specific types of records and another relative to the electronic storage of prescriptions faxed to a pharmacy. The Board considered your questions during its May 7 meeting and directed this reply.

Section §1124.B.3.d of the proposal identifies the data elements required for the records of drugs delivered by a pharmacy to patient care areas and other areas of a health care facility other than a hospital which are held for administration. Within that list of data elements, Item iv specifies "positive identification of the individual receiving the drug if it is a controlled dangerous substance." You questioned the necessity of positive identification as opposed to simple identification. The Board agreed that simple identification should be sufficient, and further, has agreed to amend the original proposal to delete the word "positive" in §1124.B.3.d.iv.

Section §1124.B.3.c of the proposal identifies the data elements required for the records of drugs compounded or prepackaged by a pharmacy for use within a health care facility other than a hospital. Within that list of data elements, Item vii specifies "positive identification of the licensed person responsible for the compounding or prepackaging of the drug." You questioned the necessity of positive identification as opposed to simple identification. The Board agreed that simple identification should be sufficient, and further, has agreed to amend the original proposal to delete the word "positive" in §1124.B.3.c.vii.

Although you did not raise a question about these same requirements in another section of the proposal relative to hospital pharmacies, the Board agreed that consistency would be achieved by making the same changes in that section, and further, has agreed to amend the original proposal to delete the word "positive" in §1509.A.3.c.vii and §1509.A.3.d.iv.

Finally, you questioned whether the proposal addresses the electronic storage of faxed prescriptions received in pharmacies serving patients in long term care facilities. In particular, you questioned whether the provisions of §1123.J would be applicable to such pharmacies or should similar language be added to §1124. The Board took note of the construction of the various sections in Chapter 11 of its rules, indicating these general provisions were applicable to

all categories of pharmacy permits unless otherwise specifically excepted either elsewhere within Chapter 11 or in other chapters. §1123.J of the proposal expands upon the existing privilege for pharmacies to use electronic imaging systems – ***from*** the single current provision for written prescription forms presented to a pharmacy ***to*** (1) oral prescriptions received in the pharmacy and then transcribed to written form in the pharmacy, (2) written prescriptions received by facsimile in the pharmacy, and (3) written prescription forms presented to the pharmacy. You noted the exclusions present in §1123.M of the proposal – hospital pharmacies which are directed to comply with Chapter 15 of the Board's rules, and other pharmacies serving patients in licensed healthcare facilities other than hospitals (e.g., long term care facilities) which are directed to comply with §1124 of the Board's rules *for those activities* [emphasis added]. The Board opined that pharmacies serving patients in long term care facilities would be obliged to comply with the provisions of §1123 unless a specific provision in §1124 was applicable, in which case the provision of §1124 would control. Since there are no provisions in §1124 relative to imaging and retention of prescription forms, the provisions of §1123.J are applicable to pharmacies serving patients in long term care facilities.

I trust this information is responsive to your inquiry and will rely on you to advise me to the contrary. Again, thank you for your interest and participation in the Board's rulemaking activity.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

June 11, 2014

Paul J D'Aunoy
204 Harang Ave
Metairie, LA 70001-4504

Re: Regulatory Project 2014-3 ~ Pharmacy Records

Dear Mr. D'Aunoy:

Thank you for taking the time to review the Board's proposed amendments to its rules relative to pharmacy records, as well as for participating in the Board's public hearing on April 29 to receive comments and testimony on the proposed amendments. During the hearing you raised a question as to the impact of the proposed amendments, if any, on the existing rules relative to the remote processing of medical orders and prescription drug orders. The Board considered your question during its May 7 meeting and directed this reply.

The proposed amendments to §1123 and the other relevant sections relate to the general topic of pharmacy records in all pharmacy permit classifications. The existing rules relative to the remote processing of medical orders and prescription drug orders are found in §1143. The Board has opined that neither section of rules (or proposed amendments thereof) is in conflict with the other. More specifically, the provision of §1143.A.1.a requiring the parties to have the same owner, or in the alternative, have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations could serve to prevent the duplication of records in both pharmacies. In the event a pharmacy has already entered into an agreement relative to remote processing, it would be prudent for that agreement to be revisited following the promulgation of these proposed amendments to the Board's rules.

I trust this information is responsive to your inquiry and will rely on you to advise me to the contrary. Again, thank you for your interest and participation in the Board's rulemaking activity.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

Person Preparing Statement:	Malcolm J Broussard Executive Director	Dept.:	Health and Hospitals
		Office:	Board of Pharmacy
Phone:	(225) 925-6481	Title:	Pharmacy Records
Return Address:	3388 Brentwood Drive Baton Rouge, LA 70809-1700	Date Rule Takes Effect:	November 1, 2014 (est.)

SUMMARY
(Use complete sentences)

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS, I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule will result in no costs or savings to local governmental units. The Board has allocated $2,000 for printing costs of the proposed rule and the final rule in state FY 15. The proposed rule changes requirements relative to pharmacy records, establishes standards for the receipt and processing of electronic prescriptions, and clarifies and updates requirements regarding confidentiality, pharmacy records and records retention.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no impact on state or local government revenue collections from the proposed rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)

The proposed rule change will affect all pharmacies with respect to their dispensing information systems. Some pharmacies already comply with the new standards and some do not. There could be a cost for some pharmacies to upgrade their information system technology, ranging from as little as $50 for a fingerprint scanner up to as much as $10,000 for a substantial systems upgrade. Pharmacies currently electing to receive and process electronic prescriptions for controlled substances are already required to comply with the new standards by the federal government. Alternatively, pharmacies may elect to maintain their current record keeping system as long as the system complies with certain provisions as detailed in §1123, Paragraph B.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will not have any effect on competition or employment.

Malcolm J Broussard
Signature of Agency Head or Designee

John D. Caplis
Legislative Fiscal Officer or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

8/5/2014
Date of Signature

July 14, 2014
Date of Signature

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberation on the proposed rule.

A. Provide a brief summary of the content of the rule (if proposed for adoption, or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

The Board proposes to amend its rules relative to pharmacy records, to establish standards for the receipt and processing of all electronic prescriptions in Louisiana pharmacies, and to clarify and update the current requirements. For those pharmacies not electing to receive or process electronic prescriptions, the proposed rule allows such pharmacies to maintain their current recordkeeping system. For those pharmacies electing to receive and process electronic prescriptions for controlled substances, they are already required to comply with these standards from the federal government. A copy of the Notice of Intent is appended.

B. Summarize the circumstances that require this action. If the Action is required by federal regulation, attach a copy of the applicable regulation.

With the federal government's establishment of security and recordkeeping standards for the generation, transmission, receipt, and processing of electronic prescriptions for controlled substances in 2010, the Board determined there should be a uniform set of standards for all electronic prescriptions, including those for controlled substances. The Board proposes to amend its current recordkeeping rules to establish similar standards for all electronic prescriptions to be received and processed by Louisiana pharmacies.

C. Compliance with Act 11 of the 1986 First Extraordinary Session:

(1) Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding.

We anticipate an increased expenditure for the printing of the proposed and final rules.

(2) If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(a) _____ Yes. If yes, attach documentation.

(b) _____ No. If no, provide justification as to why this rule change should be published at this time.

The Board receives no appropriated funds from the legislature and operates totally on self-generated funds.

D. Compliance with Act 820 of the 2008 Regular Session

(1) An identification and estimate of the number of small businesses subject to the proposed rule.

Given the criteria in the statutory definition of 'small businesses,' we are unable to specifically identify small businesses because the Board does not collect information from pharmacies concerning the number of employees or any information on sales, net worth, or other financial data. To the extent that all of the pharmacies licensed by the Board may meet the statutory definition of a small business, there are 1,832 pharmacies currently licensed by the Board.

(2) The projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The proposed rule change establishes standards for the receipt, processing and storage of electronic prescriptions and records, but allows pharmacies to maintain their current manual recordkeeping systems if they do not wish to process electronic prescriptions.

(3) A statement of the probable effect on impacted small businesses.

We anticipate no effect on small businesses that wish to maintain their current recordkeeping systems; however, there may be costs for those pharmacies electing to update their systems.

(4) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rule.

We can discern no alternative methods of achieving the same purpose of the proposed rule.

FISCAL AND ECONOMIC IMPACT STATEMENT
WORKSHEET

I. A. COSTS OR SAVINGS TO STATE AGENCIES RESULTING FROM THE ACTION PROPOSED

1. What is the anticipated increase (decrease) in costs to implement the proposed action?

COSTS	FY 14-15	FY 15-16	FY 16-17
PERSONAL SERVICES	$ 0	$ 0	$ 0
OPERATING EXPENSES	$ 2,000	$ 0	$ 0
PROFESSIONAL SERVICES	$ 0	$ 0	$ 0
OTHER CHARGES	$ 0	$ 0	$ 0
EQUIPMENT	$ 0	$ 0	$ 0
MAJOR REPAIR & CONSTR.	$ 0	$ 0	$ 0
TOTAL	$ 2,000	$ 0	$ 0
POSITIONS (#)	0	0	0

2. Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, assumptions, and methods used in calculating these costs.

The Board has allocated $2,000 for the printing of the Notice of Intent and the Final Rule in state FY 15.

3. Sources of funding for implementing the proposed rule or rule change.

SOURCE	FY 14-15	FY 15-16	FY 16-17
STATE GENERAL FUND	$ 0	$ 0	$ 0
AGENCY SELF-GENERATED	$ 2,000	$ 0	$ 0
DEDICATED	$ 0	$ 0	$ 0
FEDERAL FUNDS	$ 0	$ 0	$ 0
OTHER (Specify)	$ 0	$ 0	$ 0
TOTAL	$ 2,000	$ 0	$ 0

4. Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

The Board currently has sufficient funds budgeted and available to complete the rulemaking project.

B. COST SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED

1. Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact.

2. Indicate the source of funding of the local governmental unit that will be affected by these costs or savings.

To the extent a local governmental unit operates a pharmacy and that pharmacy elects not to accept and process electronic prescriptions as well as maintain their current recordkeeping system, we anticipate no impact on those pharmacies.

II. EFFECT ON REVENUE COLLECTIONS OF STATE AND LOCAL GOVERNMENTAL UNITS

A. What increase (decrease) in revenues can be anticipated from the proposed action?

SOURCE	FY 14-15	FY 15-16	FY 16-17
STATE GENERAL FUND	$ 0	$ 0	$ 0
AGENCY SELF-GENERATED	$ 0	$ 0	$ 0
DEDICATED FUNDS	$ 0	$ 0	$ 0
FEDERAL FUNDS	$ 0	$ 0	$ 0
LOCAL FUNDS	$ 0	$ 0	$ 0
TOTAL	$ 0	$ 0	$ 0

B. Provide a narrative explanation of each increase or decrease in revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases.

We can discern no impact on the revenue collections of state and local governmental units from the proposed rule.

III. COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS

A. What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

The proposed rule affects all pharmacies licensed by the Board and updates the recordkeeping requirements in such pharmacies. For those pharmacies electing not to accept or process electronic prescriptions, those pharmacies may elect to maintain their current recordkeeping systems. For those pharmacies already accepting and processing electronic prescriptions for controlled substances, those pharmacies must comply with the federal standards applicable to such activities and are already in compliance with the standards in the proposed rule.

For those pharmacies that wish to begin accepting and processing electronic prescriptions, they may or may not need to update their computer hardware and/or their software. The cost for that update will depend on their current system capability. The update might require as little as, for example, a fingerprint reader attached to the current computer, which could cost less than $50. Conversely, a computer system not already updated in several years might require a substantial upgrade in technology which could cost as much as $10,000.

Also provide an estimate and a narrative description of any impact on receipts and/or income (revenue) resulting from this rule or rule change to these groups.

The proposed rule will not have any impact on receipts or revenue.

IV. EFFECTS ON COMPETITION AND EMPLOYMENT

Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include a summary of any data, assumptions and methods used in making these estimates.

The proposed rule will not have any impact on competition or employment.

Malcolm J Broussard
Signature of Agency Head or Designee

Malcolm J Broussard, Executive Director
Typed Name and Title of Agency Head or Designee

July 14, 2014
Date of Signature

Potpourri Notice

Department of Health and Hospitals
Board of Pharmacy

Pharmacy Records (LAC 46:LIII.Chapters 11, 12, and 15)

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Board of Pharmacy published its Notice of Intent in the March 2014 edition of the Louisiana Register, specifying its proposal to amend several sections within *Chapter 11 – Pharmacies*, as well as Section 1213 in *Chapter 12 – Automated Medication Systems* and Sections 1503 and 1509 in *Chapter 15 – Hospital Pharmacy* to update the rules relative to pharmacy records and recordkeeping requirements. As indicated in the notice, the Board conducted a public hearing on April 29 to receive comments and testimony on the proposal.

During the Board's consideration of those comments and testimony during its subsequent meeting on May 7, they agreed with a request to revise the original proposal by deleting the requirement for positive identification in favor of simple identification for two specific types of records maintained by pharmacies. In particular, the Board has agreed to revise the original proposal by deleting the word "positive" in the following four locations in the original proposal:

- §1124.B.3.c.vii;
- §1124.B.3.d.iv;
- §1509.A.3.c.vii; and
- §1509.A.3.d.iv.

The Legislative Fiscal Office has evaluated the impact of the proposed revisions of the original proposal and has opined the suggested revisions would not adversely increase any cost to the stakeholders, and may very well lower any costs associated with implementation of positive identification.

Interested persons may submit written comments to Malcolm J Broussard, Executive Director, Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700. He is responsible for responding to inquiries regarding this proposed rule as well as these proposed revisions to the original proposal. A public hearing on these proposed revisions to the original proposal is scheduled for Tuesday, September 30, 2014 at 9:00 a.m. in the Board office. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12:00 noon that same day.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter B. Pharmacy Records

…

§1124. Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other than Hospitals

…

B. Drug Distribution and Control

…

3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:

…

c. A record of all drugs compounded or prepackaged for use only within that facility, which shall include at least the following:

…

vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.

d. A record of the distribution of drugs to patient care areas and other areas of the facility held for administration, which shall include at least the following:

…

iv. Identification of the individual receiving the drug if it is a controlled dangerous substance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR

…

Chapter 15. Hospital Pharmacy

…

§1509. Drug Distribution and Control

A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs. The staff of the hospital pharmacy shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.

…

3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:

…

c. A record of all drugs compounded or prepackaged for use only within that hospital, which shall include at least the following:

…

vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.

d. A record of the distribution of drugs to patient care areas and other areas of the hospital held for administration, which shall include at least the following:

…

iv. Identification of the individual receiving the drug if it is a controlled dangerous substance.

…

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2903 (October 2003), effective January 1, 2004, amended LR

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

Summary of Testimony & Public Comments
re
Regulatory Project 2014-3 ~ Pharmacy Records
at
September 30, 2014 Public Hearing

During the comment period identified in the *Potpourri Notice* – August 20 through 12 noon on September 30 – the Board received no written comments. During the public hearing conducted on the morning of September 30, three commentators appeared to ask questions. No objections were raised, nor were there any requests for further changes.

1. Jason Chou, Director of Pharmacy at, and appearing on behalf of, Ochsner Foundation Hospital in New Orleans, La.

Dr. Chou asked the time frame for implementation of the proposed rule change.

2. Paul Menasco, Director of Pharmacy at, and appearing on behalf of, Ochsner Medical Center – Westbank in Terrytown, La.

Mr. Menasco asked the record retention requirement for the records identified in the proposed rule as well as the amount of time permitted to respond to a request for those records.

3. Wendy Gaudet, Pharmacist at, and appearing on behalf of, Our Lady of the Lake Hospital in Baton Rouge, La.

Dr. Gaudet questioned the Board's definition of 'simple identification' as opposed to 'positive identification.'

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

October 2, 2014

Jason D. Chou
6014 Canal Blvd.
New Orleans, LA 70124-2909

Re: Regulatory Project 2014-3 ~ Pharmacy Records

Dear Dr. Chou:

Thank you for participating in the Board's public hearing on September 30, during which you asked questions about the Board's proposed rule changes. With respect to your questions, we now confirm our responses thereto:

- With respect to the provisions of §1509.A.3, you questioned the time frame for implementation of any new recordkeeping requirements.

  Board's Response:

  The state's Administrative Procedure Act (APA) requires the Board to follow the APA procedures for all of its rulemaking activities. The final step in the promulgation process is the publication of the proposal as a Final Rule in the Louisiana Register, which is published on the 20th day of each month. In the absence of any indicator to the contrary, the effective date of a Final Rule is the date of its publication in the state register. Although it is possible the promulgation process may conclude with a printing of the Final Rule sometime during the remainder of Calendar Year 2014, staff intends to recommend a slightly delayed effective date of January 1, 2015. On the presumption the Board agrees with that recommendation, staff will insert the delayed effective date in the preamble of the Final Rule when it is published in the state register.

- Although not the subject of the proposed revision noticed for hearing at this time, you questioned the provisions of §1509.A.3.c.ii in the original proposal, relative to the recording of certain manufacturer or distributor information relative to the compounding of sterile preparations for later use by patients in your facility.

  Board's Response:

  The information specified is required to be recorded and maintained, and a compounding record would be sufficient. It would not be necessary to rely on the product label as the only record of that information.

We trust this information is responsive to your inquiries, and will rely on you to advise us to the contrary. Thank you, again, for participating in the public hearing.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

October 2, 2014

Paul D. Menasco
528 Phosphor Ave.
Metairie, LA 70005-3234

Re: Regulatory Project 2014-3 ~ Pharmacy Records

Dear Mr. Menasco:

Thank you for participating in the Board's public hearing on September 30, during which you asked questions about the Board's proposed rule changes. With respect to your questions, we now confirm our responses thereto:

- With respect to the records referenced in the original proposal as well as the proposed revisions to that original proposal, for how long are pharmacies required to maintain those records?

  Board's Response:

  The Louisiana Pharmacy Practice Act, more specifically at La. R.S. 37:1229, requires pharmacies to maintain all required records for a minimum of two years. Moreover, the Louisiana Administrative Code, more specifically at LAC 46:LIII.1121.A of the Board's current rules, specifies the same two year record retention requirement.

- With respect to those same records, how much time does a pharmacy have to respond to a request for its records by the Board?

  Board's Response:

  The Board's current rules, more specifically at LAC 46:LIII.1119 of the current rule, or at LAC 46:LIII.1121.A.2 of the proposed rule, requires a pharmacy to produce records requested by the Board within seventy-two (72) hours of the request by the Board or its agent.

We trust this information is responsive to your inquiries, and will rely on you to advise us to the contrary. Thank you, again, for participating in the public hearing.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ Facsimile 225.925.6499
www.pharmacy.la.gov ~ E-mail: info@pharmacy.la.gov

October 2, 2014

Wendy R. Gaudet
9057 Fox Gate Dr.
Baton Rouge, LA 70809-5245

Re: Regulatory Project 2014-3 ~ Pharmacy Records

Dear Dr. Gaudet:

Thank you for participating in the Board's public hearing on September 30, during which you asked a question about the Board's proposed revision to its original proposal. With respect to your question, we now confirm our response thereto:

- With respect to the records referenced in the proposed revision, the Board proposed to delete the requirement for positive identification in favor of simple identification. With respect to the simple identification, how does the Board define 'identification?'

  Board's Response:

  Since that term is not specifically defined in the proposal, we would suggest reliance on the dictionary published by Webster.

We trust this information is responsive to your inquiry, and will rely on you to advise us to the contrary. Thank you, again, for participating in the public hearing.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 11. Pharmacies

…

Subchapter B. Pharmacy Records

§1119. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:
"Department" means the Louisiana Department of Health and Hospitals or its successor.
"Password" means a private identification that is created by a user to obtain access to an electronic pharmacy information system.
"Personal identifier" means a unique user name or number for identifying and tracking a specific user's access to a pharmacy information system such as social security number, user identification number, or employee number.
"Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a prescription drug.

a. A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
   i. A manual signature on a hard copy record;
   ii. A magnetic card reader;
   iii. A bar code reader;
   iv. A thumbprint reader or other biometric method;
   v. A proximity badge reader;
   vi. A register in which each individual pharmacist dispensing a prescription shall sign a log each day, attesting to the fact that the information entered into the electronic record keeping system has been reviewed that day, and is correct as stated.
   vii. A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the prescription drug. The printout must be maintained for two years and made available on request to an agent of the board.

b. A method relying on a magnetic card reader, a bar code reader, or a proximity badge reader must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR

§1121. General Requirements

A. Requirements.
   1. All records relating to the practice of pharmacy shall be uniformly maintained for a period of two years, be readily available, and promptly produced upon request for inspection by an agent of the board during regular business hours.
   2. All records required by the laws and regulations of the board shall be provided to the board, or its agents, within seventy-two (72) hours of request, unless a shorter period is required, as determined by the board or its agent.
   3. The failure to produce any pharmacy records requested by the board or its agent within seventy-two (72) hours of such request shall substantiate a violation of R.S. 37:1241(A)(22).

B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all prescription drug transactions, consisting of:
   1. Acquisition records – invoice receipts of drugs acquired;
   2. Disposition records – drugs dispensed pursuant to prescription orders, administered pursuant to medical orders, or distributed pursuant to purchase orders, and
   3. Inventory records – drugs in current possession.

C. Retention. Except as provided in Section 1123, all records required by this Chapter and by Louisiana law shall be retained for a minimum of two years from the most recent transaction. The failure to retain such records for at least two years shall substantiate a violation of R.S. 37:1229.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR

§1123. Records

A. There shall be positive identification of the pharmacist, intern, technician, or technician candidate responsible for performing all activities related to the practice of pharmacy including, but not limited to:
   1. Prescription information entered into the pharmacy information system;
   2. Prospective drug utilization review;
   3. Prescription dispensing;
   4. Administration of immunizations.

B. A pharmacy may use one of the following types of pharmacy information systems:
   1. A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system shall require the manual signature or initials of a pharmacist on a hard copy record as specified in Paragraph E of this Section.
   2. An electronic recordkeeping system that complies with the provisions of 21 CFR 1311 and documents the positive identification of the pharmacist responsible for the practice of pharmacy. Such systems shall provide for routine backups at least once per day.

C. All pharmacy information systems shall be capable of providing immediate retrieval (via display and hard copy printout or other mutually agreeable transfer media) of patient profile information for all prescriptions dispensed within the previous two years. This information shall include the following minimum data:
   1. The original prescription number;
   2. Date of issuance of the original prescription order by the prescriber;
   3. Date of dispensing by the pharmacist;
   4. Full name and address of the patient;
   5. Full name and address of the prescriber;
   6. Directions for use;
   7. The name, strength, dosage form, and quantity of the drug prescribed;
   8. The quantity dispensed if different from the quantity prescribed;
   9. The pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in §515 of these rules, and the pharmacist responsible for dispensing;
   10. The total number of refills authorized by the prescriber; and
   11. The refill history of the prescription as defined in Paragraph D of this Section.

D. The refill history of the prescription record maintained in the pharmacy information system shall include, but is not limited to:
   1. The prescription number;
   2. The name and strength of the drug dispensed;
   3. The date of the refill or partial fill;
   4. The quantity dispensed;
   5. The pharmacist responsible for prospective drug utilization review as defined in §515 of these rules, and the pharmacist responsible for dispensing each refill;
   6. The total number of refills or partial fills dispensed to date for that prescription order

E. The hard copy documentation required pursuant to Paragraph (B)(1) of this Section shall be provided by each individual pharmacist who makes use of such system by signing a statement attesting to the fact that the prescription information entered into the computer is correct as displayed.

F. Backup Support System
   1. The pharmacy information system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.

2. In the event the pharmacy information system experiences down time, a record of all refills dispensed during such time shall be recorded and then entered into the pharmacy information system as soon as it is available for use. During the time the pharmacy information system is not available, prescriptions may only be refilled if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

G. A pharmacy purging a pharmacy information system of prescription records shall develop a method of recordkeeping capable of providing retrieval (via display, hard copy printout, or other mutually agreeable transfer media) of prescription order information for all prescriptions filled or refilled within the previous two years. This information shall include, at a minimum, the following data:
    1. Pharmacy name and address;
    2. Original prescription number;
    3. Date of issuance of the original prescription order by the prescriber;
    4. Date of original dispensing by the pharmacist;
    5. Full name and address of the patient;
    6. Full name and address of the prescriber;
    7. Directions for use;
    8. Name, strength, dosage form, and quantity of the drug prescribed;
    9. Quantity dispensed if different from the quantity prescribed;
    10. Total number of refills authorized by the prescriber;
    11. Total number of refills dispensed to date for that prescription order;
    12. Date of each refill;
    13. Name or initials of each individual dispensing pharmacist.

H. A log shall be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. At a minimum, the log shall contain the following information:
    1. Date and time of change;
    2. Change(s) made;
    3. Pharmacist making the change.

I. Prescriptions entered into a pharmacy information system but not dispensed shall meet all of the following requirements:
    1. The complete prescription information shall be entered in the computer system;
    2. The information shall appear in the patient's profile; and
    3. There is positive identification, in the pharmacy information system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system.

J. With respect to oral prescriptions received in the pharmacy and then transcribed to written form in the pharmacy, or written prescriptions received by facsimile in the pharmacy, or written prescriptions presented to the pharmacy, a pharmacy may use an electronic imaging system to preserve such prescriptions, but only if:
    1. The system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription form;
    2. Any notes of clarification of and alterations to a prescription shall identify the author and shall be directly associated with the electronic image of the prescription form;
    3. The image of the prescription form and any associated notes of clarification to or alterations to a prescription are retained for a period of not less than two years from the date the prescription is last dispensed;
    4. Policies and procedures for the use of an electronic imaging system are developed, implemented, reviewed, and available for board inspection; and
    5. The prescription is not for a controlled dangerous substance listed in Schedule II

K. Filing and Retention of Prescription Forms
    1. Written prescription forms (including transcriptions of verbal prescriptions received in the pharmacy, prescriptions received by facsimile in the pharmacy, as well as written prescription forms presented to the pharmacy) shall be assembled and stored in prescription number sequence. Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately from all other prescriptions. Where multiple medications are ordered on a single prescription form and includes one or more controlled dangerous substances listed in Schedule II, then such forms shall be filed with other Schedule II prescriptions. These original hard copy prescription forms shall be retained in the prescription department for a minimum of two years following the most recent transaction.

2. For those pharmacies utilizing an electronic imaging system as described in Paragraph J of this Section, written prescription forms may be assembled and stored in prescription number sequence, or in the alternative, a date scanned sequence. Further, these original hard copy prescriptions shall be retained in the prescription department for a minimum of one year following the most recent transaction.
3. Prescription forms received as an electronic image or electronic facsimile directly within the pharmacy information system shall be retained within the information system for a minimum of two years following the most recent transaction. Further, the pharmacy may produce a hard copy of the prescription form but shall not be required to do so merely for recordkeeping purposes.
4. Electronic prescriptions – those generated electronically by the prescriber, transmitted electronically to the pharmacy, and then received electronically directly into the pharmacy information system – shall be retained within the information system for a minimum of two years following the most recent transaction. The pharmacy may produce a hard copy of the prescription, but shall not be required to do so merely for recordkeeping purposes.

L. Patient Profiles

All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.

1. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, document, and maintain at least the following records:
    a. The patient's data record, which should consist of, but is not limited to, the following information:
        i. Full name of the patient for whom the drug is intended;
        ii. Residential address and telephone number of the patient;
        iii. Patient's date of birth;
        iv. Patient's gender;
        v. A list of current patient specific data consisting of at least the following:
            (a) Known drug related allergies,
            (b) Previous drug reactions,
            (c) History of or active chronic conditions or disease states,
            (d) Other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices.
        vi. The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug.
    b. The patient's drug therapy record, which shall contain at least the following information for all the prescriptions that were filled at the pharmacy:
        i. Name and strength of the drug or device;
        ii. Prescription number;
        iii. Quantity dispensed;
        iv. Date dispensed;
        v. Name of the prescriber;
        vi. Directions for use.
    c. Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.

M. Exceptions

The provisions of this Section shall not apply to the following:

1. Pharmacies permitted as hospital pharmacies by the board shall comply with the provisions of Chapter 15 of these rules.
2. Other pharmacies providing medications and services to patients within facilities other than hospitals licensed by the department shall comply with the provisions of Section 1124 of these rules for those activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, amended LR 36:755 (April 2010), amended LR

§1124. Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other

than Hospitals

A. Definitions

Dispensing of a drug pursuant to an inpatient prescription – the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated medication system meeting the requirements of Chapter 12 of these rules, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given the final approval to the patient specific order in the system.

Electronic drug record keeping system – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

Inpatient – a person receiving health care services within a healthcare facility other than a hospital licensed by the department.

Inpatient Prescription – a written, electronic or oral order for a drug for use in treating a patient within a healthcare facility other than a hospital licensed by the department.

Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

Personal identifier – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number

Positive identification –

a. has the same meaning as defined in Section 1119 of these rules, except that a specific facility having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:
    i. adequate audit controls are in place to detect and deter drug diversion;
    ii. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
    iii. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
    iv. an ongoing quality assurance program is in place to ensure that (a) through (c) of this term are being fulfilled and reviewed; and
    v. appropriate policies and procedures are in place to address items (a) through (d) of this term.

b. All of the above notwithstanding, however, positive identification as defined in Section 1119 of these rules shall always be used to document the:
    i. Dispensing, compounding, or prepackaging of a drug;
    ii. Removal and possession of a controlled substance to administer to a patient; and
    iii. Waste of a controlled substance.

B. Drug Distribution and Control

The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs.

1. Procedure Manual. The pharmacist-in-charge shall maintain defined procedures for the safe and efficient distribution of medications and pharmacy care. A current copy of the manual shall be available for board inspection upon request.
2. Inventories. The pharmacist-in-charge shall be responsible for the performance of an annual inventory of all controlled dangerous substances within his span of control, in compliance with the provisions of Section 2733 of these rules.
3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
    a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
    b. All drug orders and records relating to the practice of pharmacy.
        i. Records of drugs dispensed shall include, but are not limited to:
            (a) The name, strength, and quantity of drugs dispensed;
            (b) The date of dispensing;
            (c) The name of the inpatient to whom, or for whose use, the drug was dispensed; and
            (d) Positive identification of all pharmacists involved in the dispensing.

ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
(a) The name of the inpatient to whom, or for whose benefit, the activity was performed;
(b) The nature of the pharmacy practice activity performed;
(c) The results of the activity, if applicable; and
(d) Positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist.
iii. Records of drugs dispensed to patients for use outside the facility shall be maintained in compliance with Section 1123 of these rules.

c. A record of all drugs compounded or prepackaged for use only within that facility, which shall include at least the following:
i. Name of drug, strength, quantity, and dosage form;
ii. Manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
iii. Manufacturer's or distributor's name, if a generic drug is used;
iv. Pharmacy control number;
v. Manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
vi. Pharmacy's expiration date or beyond-use date;
vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.

d. A record of the distribution of drugs to patient care areas and other areas of the facility held for administration, which shall include at least the following:
i. The name, strength, dosage form, and amount of the drug distributed;
ii. The area receiving the drug;
iii. The date distributed;
iv. Identification of the individual receiving the drug if it is a controlled dangerous substance;
v. The area of the facility receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
(a) Name of the patient;
(b) Name, dosage form, and strength when applicable of the drug;
(c) Date and time the drug was administered;
(d) Quantity administered;
(e) Positive identification of the personnel administering the drug.

e. A log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
i. Date and time of change;
ii. Changes made;
iii. Person making the change.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR

§1125. Security and Confidentiality

A. The holder of the pharmacy permit shall provide adequate safeguards against improper, illegal, or unauthorized manipulation or alteration of any records in the pharmacy information system.

B. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential information. If confidential health information is not transmitted directly between a pharmacist and a practitioner, but is transmitted through a data communications device, the confidential health information may not be accessed, maintained, or altered by the operator of the data communications device. Confidential information is privileged and may be released only subject to federal privacy laws and regulations, and subject to applicable Louisiana statutes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23.1312, (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, amended LR

§1127. Register

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, repealed LR

§1129. Confidentiality

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004, repealed LR

…

Chapter 12. Automated Medication Systems

…

§1213. Records

A. Records and/or electronic data kept by the system shall meet the following requirements:
   1. …
   2. In the event controlled substances are stored in the system, the records shall include the positive identification (as defined in Section 1119 of the Board's rules) of the personnel retrieving and administering the controlled substance to the patient.
   3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000), effective July 1, 2000, amended LR

…

Chapter 15. Hospital Pharmacy

…

§1503. Definitions

Dispensing of a drug pursuant to a hospital prescription – the professional review by a pharmacist required to place a specific drug in final association with the name of a particular hospital patient pursuant to the lawful order of a prescriber. In the case of an automated medication system meeting the requirements of Chapter 12 of these rules, the final association with the name of a particular hospital patient will be deemed to have occurred when the pharmacist has given the final approval to the patient specific order in the system.
Electronic drug record keeping system – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.
Hospital Patient – a person receiving health care services within a hospital facility.
Hospital Pharmacy – …
Hospital Prescription – a written, electronic or oral order for a drug for use in treating a hospital patient.
Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

Personal identifier – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number

Positive identification –

1. has the same meaning as defined in Section 1119 of these rules, except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:
    a. adequate audit controls are in place to detect and deter drug diversion;
    b. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
    c. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
    d. an ongoing quality assurance program is in place to ensure that all three provisions cited above in this definition are being fulfilled and reviewed; and
    e. appropriate policies and procedures are in place to address all four provisions cited above in this definition.
2. All of the above notwithstanding, however, positive identification as defined in Section 1119 of these rules shall always be used to document the:
    a. Dispensing, compounding, or prepackaging of a drug;
    b. Removal and possession of a controlled substance to administer to a patient; and
    c. Waste of a controlled substance.

Unit Dose – …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, amended LR 33:1132 (June 2007), amended LR

…

§1509. Drug Distribution and Control

A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs. The staff of the hospital pharmacy shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.

1. Procedure Manual
   …
2. Inventories
   …
3. Records
   The pharmacist-in-charge shall be responsible for maintaining the following records:
    a. A record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
    b. All drug orders and records relating to the practice of pharmacy.
        i. Records of drugs dispensed shall include, but are not limited to:
            (a) The name, strength, and quantity of drugs dispensed;
            (b) The date of dispensing;
            (c) The name of the hospital patient to whom, or for whose use, the drug was dispensed; and
            (d) Positive identification of all pharmacists involved in the dispensing.
        ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
            (a) The name of the hospital patient to whom, or for whose benefit, the activity was performed;
            (b) The nature of the pharmacy practice activity performed;
            (c) The results of the activity, if applicable; and
            (d) Positive identification of all pharmacists involved in the activity;

identifying the function performed by each pharmacist.

iii. Records of drugs dispensed to patients for use outside the hospital shall be maintained in compliance with Section 1123 of these rules.

c. A record of all drugs compounded or prepackaged for use only within that hospital, which shall include at least the following:
   i. Name of drug, strength, quantity, and dosage form;
   ii. Manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
   iii. Manufacturer's or distributor's name, if a generic drug is used;
   iv. Pharmacy control number;
   v. Manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
   vi. Pharmacy's expiration date or beyond-use date;
   vii. Identification of the licensed person responsible for the compounding or prepackaging of the drug.

d. A record of the distribution of drugs to patient care areas and other areas of the hospital held for administration, which shall include at least the following:
   i. The name, strength, dosage form, and amount of the drug distributed;
   ii. The area receiving the drug;
   iii. The date distributed;
   iv. Identification of the individual receiving the drug if it is a controlled dangerous substance;
   v. The area of the hospital receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
      (a) Name of the patient;
      (b) Name, dosage form, and strength when applicable of the drug;
      (c) Date and time the drug was administered;
      (d) Quantity administered;
      (e) Positive identification of the personnel administering the drug.

e. A log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
   i. Date and time of change;
   ii. Changes made;
   iii. Person making the change.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004, amended LR

…